RUSH

Policy

Title	Policy on Governmental and Sponsor Audits
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PolicyType	Research Affairs
Category	Research Compliance
Subcategory1	
Subcategory2	
Subcategory3	
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Contact	Stephanie Guzik
Applies To	Rush Investigators/Study Staff
Purpose	
Executive Summary	
Definitions	
Equipment	
Information	

Policy

Governmental agencies perform periodic audits and investigations of research conducted at Rush University Medical Center ("Rush"). The purpose is to ensure compliance with Good Clinical Practices and other applicable regulatory requirements. Governmental agencies that conduct audits or investigations include, but are not limited to: the United States Food and Drug Administration, the United States Department of Health and Human Services, the United States Department of Justice, the United States Department of Agriculture, and other Federal or State agencies. Sponsors of sponsored research projects may also perform periodic audits or investigations of research conducted at Rush under sponsored research agreements.

Upon receiving notice of an audit or investigation, the Principal Investigator shall notify the Study Coordinator, the Department Chairman and Administrative Director of the department where the study is performed, and the Office of Research Compliance of the audit or investigation and will cooperate with the governmental agency or sponsor who is conducting the audit or investigation.

Outcome

Guidelines

Responsibility and Procedure

When notified by a governmental agency or sponsor of an audit or investigation, the Principal Investigator will immediately notify the Office of Research Compliance,

the Study Coordinator, and the Department Chairman and the Administrative Director of the department where the study is performed. The notification shall include:

- The name of the governmental agency or sponsor requesting
- the audit or investigation;
- The expected date and time-frame for the audit or investigation, if known;
- The reason for the audit or investigation, if known;
- Any potential problem areas or incidents of which the Institutional Review Board has not been notified.

The Principal Investigator will request a meeting with the study staff involved in the research project ("Study Staff") and the Director of Research Compliance (or his/her designee) to determine a timeline to obtain, review, update, and pre-audit the study.

When the inspector arrives, the Director of Research Compliance (or his/her designee) will be present for the initial meeting. The Principal Investigator should assign a member of the Study Staff ("PI's Designee") for ongoing administrative support to the inspector, such as providing responses to questions, and obtaining or making copies of documents. The PI's Designee shall copy and label any documents requested by the inspector for the PI's research file. The PI's Designee shall cooperate with the inspector and remain accessible to the inspector. The PI or the PI's Designee will arrange to meet with the inspector at least once each day to review any observations and provide any additional information for clarification to the inspector.

Upon conclusion of the audit or investigation, the Principal Investigator or the PI's Designee and the Director of Research Compliance (or his/her designee) will be available to address any final concerns of the inspector.

The Principal Investigator shall prepare a timely written response to the audit or investigation if required by the governmental agency or sponsor. For example, the Food and Drug Administration (FDA) typically requests a response 14 calendar days from the last day of the onsite inspection unless otherwise specified. The Director of Research Compliance (or his/her designee) shall review the PI's response prior to submission to the governmental agency or sponsor.

Regulatory Elements

Related Policies

Reference Last reviewed: 12/23/2011

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